K012290
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SEP 2 8 2001

510(k) SUMMARY
3D Med Co., Ltd.
Rapidia®

1. Submitter Name and Address

Mr. Jae Jeong Choi
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REPUBLIC OF KOREA

Telephone: 82-2-889-1765
Date Prepared: July 19, 2001

2. Device Name

Proprietary Name: Rapidia®
Common/Usual Name: Image processing and 3D visualization system
Classification Name: Picture archiving and communications system

3. Predicate Device

Plug'n View 3D (K993654)

4. Intended Use

The Rapidia® is a software package intended for viewing and manipulating DICOM-compliant medical images from CT (computerized tomography) and MR (magnetic resonance) scanners. Rapidia can be used for real-time viewing, image manipulation, segmentation, 3D volume and surface rendering, virtual endoscopy, and reporting.

5. Device Description

Rapidia® is a fast, practical and accurate tool for 3D (three dimensional) and 2D (two dimensional) viewing and manipulation of CT and MRI images using the most advanced graphics rendering technology. The proposed software provides 3D volume rendering (VR), maximum/minimum intensity projection (MIP/MinIP), surface shaded display (SSD), multi-planar reconstruction (MPR), virtual endoscopy, 2D image editing and segmentation (2D), and issues reports.

6. Technological Characteristics

The proposed and predicate devices are both software programs that can be used for manipulation of DICOM-compliant CT and MRI images. The proposed and predicate software can be operated from a personal computer. Differences between the proposed and predicate devices are limited to the availability of certain image viewing and editing features.

7. Performance Testing

The proposed Rapidia® software conforms to DICOM (Digital Imaging and Communications in Medicine) Version 3. Validation testing was provided that confirms that Rapidia® performs all input functions, output functions, and all required actions according to the functional requirements specified in the Software Requirements Specification (SRS).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

3D Med Co., Ltd.
% Cynthia J. M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K012290
Trade/Device Name: Rapidia® Image Processing System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 19, 2001
Received: July 20, 2001

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012290

Device Name: Rapidia®

Indications For Use:

Rapidia® is a software package intended for viewing and manipulating DICOM-compliant medical images from CT and MR scanners. Rapidia® can be used for real-time viewing, image manipulation, segmentation, 3D volume and surface rendering, virtual endoscopy, and issuing reports.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012290

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)